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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,839	03/07/2001	Toshihiro Shimizu	2535US1P	7614

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/800,839	Shimizu et al.
Examiner	**Art Unit**
Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 15, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7 and 9-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 9-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1.5 & 5*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment A filed 03/07/01, Information Disclosure Statement filed 03/07/01 and 01/15/02, Request for Extension of Time filed 01/15/02, Declaration under 37 CFR§1.132 filed 01/15/02, and Amendment B filed 01/15/02.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 20 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 18, and 19 of copending Application No. 09/403,429. Although the conflicting claims are not identical, they are not patentably distinct from each other. While applicant cancelled claim 8 in a Preliminary Amendment dated 03/07/01 to delete lansoprazole and to overcome the double patenting rejection, newly submitted Amendment adding claim 20, which refers to the use of lansoprazole.

Although the claim does not specifically claimed lansoprazole as an active agent, specification page 28 discloses the active agent useful for the treatment of digestive ulcer, gastritis, or reflux esophagitis (being claimed) is lansoprazole. Hence, the concept and the scope of the claim is clearly obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-12, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shimizu et al. US 6,299,904 (the examiner relies on the priority date of this reference; until the translation is provided, the patentability will be reconsidered).

Ohno teaches a solid pharmaceutical composition in powder or granular that can be made into tablet suitable for buccal administration (column 2, lines 13-61). The composition comprising active ingredient; sugar, e.g., mannitol or erythritol; and disintegrant, e.g., low substituted hydroxypropyl cellulose at about 1-15 parts by weight base on 100 parts by weight of

the solid composition (columns 2 and 5). The active ingredient can be selected from various classes that is disclosed in columns 3-4. Column 6, lines 59-67 further teaches the dissolution of the tablet, which can be completely dissolved in about 0.1 to 1.0 minute.

Ohno is silent as to the teaching of the claimed active ingredients.

Shimizu teaches buccal disintegration tablet comprising active agents, e.g., manidipine HCl, pioglitazone HCl, candesartan cilexetil, and voglibose. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Ohno's formulation using the active ingredients in view of the teaching of Shimizu. The reason for this modification is to obtain a pharmaceutical preparation having the above active ingredients for oral administration. The unexpected result would be a fast disintegrating tablet with improved disintegrability and/or dissolubility useful for buccal administration.

Response to Arguments

4. Applicant's arguments filed 01/15/02 have been fully considered but they are not persuasive. The examiner maintains the original 102(b) and 103(a) rejections.

Applicant argues that Ohno does not teach a low-substituted hydroxypropyl cellulose (L-HPC) having 5% by weigh or more to less than 7% by weight. However, applicant has provide no evidence establishing that the L-HPC used by Ohno has a detrimental effect upon obtaining a rapid disintegrable tablet. Applicant's attention is directed to Ohno's teaching at column 6, lines 62-67, wherein tablet that is completely dissolved within the ranges of about 6 seconds to 60

seconds has been obtained. Hence, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable L-HPC to obtain a fast disintegrating tablet as taught by Ohno.

Applicant argues that Shashoua includes active ingredients only as agents to be conjugated to DHA. There is no teaching or suggestion of non-conjugated active ingredients, or any thing of suggestion of active ingredients having a sugar and L-HPC. In response to applicant's argument that Shashoua fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-conjugated lansoprazole) is not recited in the generic claims. Applicant claims recite "lansoprazole". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Shashoua does not teach or suggest any solid preparations of active ingredients having a sugar and low substituted hydroxypropyl cellulose. Contrary to the applicant's argument, Shashoua is relied upon solely for the teaching of active ingredient, e.g., lansoprazole, pioglitazone, candesartan, and manidipine in an oral dosage form selected from capsules, tablets, sachets, and lozenges (column 49, lines 28-44).

The Declarations under 37 CFR§1.132 filed 01/15/02 have been considered but fails to overcome the rejection of claims 1-7, and 9-20. Both Declarations are unpersuasive because they provide no evidence to establish that the L-HPC of 5% has any unusual and/or unexpected results. Applicant's Declaration disclosed that the L-HPC used in Ohno's comparative examples

3, 4, and 5 was 10.0 % by weight or more to less than 12.9 % by weight, which were far less effective than the preparations of the invention which did not include any L-HPC (tables 2, 4, and 6). Applicant claimed rapidly disintegrable, Ohno teaches fast disintegrating tablet. In any event, the term "rapid disintegrable" does not envision and/or limit the scope of the claims to a range 5 to 50 seconds. Applicant's attention is directed to Ohno's teaching at column 6, lines 62-67, wherein tablet that is completely dissolved within the ranges of about 6 seconds to 60 seconds. Ohno's teachings are relied upon within the four walls patent, Ohno cannot be limited to his best mode as described in the examples. Accordingly, the Declaration does not establish superior results over the teachings of Ohno.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600